DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-057/S-002

Organon Inc.
Attention: Peter Stokman
Associate Director, Regulatory Affairs
375 Mount Pleasant Avenue
West Orange, NJ 07052

Dear Mr. Stokman:

Please refer to your supplemental new drug application dated March 26, 2001, received March 27, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Antagon™ (ganirelix acetate) Injection.

This "Changes Being Effected in 30 days" supplemental new drug application provides for the following changes to the **DOSAGE AND ADMINISTRATION** and **Directions for Using Antagon™ (ganirelix acetate) Injection** sections of the Package Insert:

DOSAGE AND ADMINISTRATION

> After initiating FSH therapy on Day 2 or 3 of the cycle, Antagon™ (ganirelex acetate) Injection 250 µg may be administered subcutaneously once daily during the ~~early to mid follicular phase~~ mid to late follicular phase.

Directions for Using Antagon™ (ganirelex acetate) Injection

> 5. ~~Remove needle cover.~~ With syringe held upward, remove needle cover.

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text and with the minor editorial revisions listed below. Accordingly, the supplemental application is approved effective on the date of this letter. Please revise as follows:

DOSAGE AND ADMINISTRATION

> After initiating FSH therapy on Day 2 or 3 of the cycle, Antagon™ (ganirelex acetate) Injection 250 µg may be administered subcutaneously once daily during the mid to late portion of the follicular phase.

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the submitted draft labeling (package insert submitted March 26, 2001). These revisions are terms of the approval of this application.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 21-057/S-002." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Jeanine Best, M.S.N., R.N., Regulatory Project Manager, at (301) 827-4260.

Sincerely,

{See appended electronic signature page}

Susan Allen, M.D., M.P.H.
Director
Division of Reproductive and Urologic Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research